UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,738	06/19/2000	H. William Bosch	029318/0615	3886

7590 10/02/2002

Foley & Lardner
Washington Harbor
Suite 500
3000 K Street NW
Washington, DC 20007-5109

EXAMINER
HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 10/02/2002 17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/597,738	Applicant(s) BOSCH ET AL.	
	Examiner Mina Haghighatian	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-119* is/are pending in the application.

4a) Of the above claim(s) *65-78,82,83 and 102-117* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-64,79-81,84-101,118 and 119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *65-78,82,83 and 102-117* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 51-64, 79-81, and 118 rejected under 35 U.S.C. 103(a) as being unpatentable over Wood et al (6,264,922 B1).

Wood et al teach an aerosol comprising droplets of an aqueous dispersion of nanoparticles, said nanoparticles comprising insoluble therapeutic or diagnostic agent particles having a surface modifier on the surface thereof. There is also disclosed a method of making the aerosol and methods of treatment and diagnosis using the aerosol (see abstract). The droplets in the aerosols typically have a size less than about 50 microns in diameter although droplets of a much smaller size are possible. The aerosols are made by nebulizing the nanoparticle containing solution using a variety of known nebulizing techniques (col. 2, line 52 to col. 3, line 7).

Wood discloses that the therapeutic agent must be poorly soluble, which means a solubility in the liquid dispersion medium of less than about 10 mg/ml, and preferably of less than about 1 mg/ml. The preferred liquid dispersion medium is water (col. 3, lines 29-44). Suitable therapeutic or diagnostic agents are disclosed in column 2, lines 45-65. suitable surface modifiers are disclosed in column 4, line 44 to end of column 6.

Wood also discloses that by "an effective average particle size of less than about 1000 nm" is meant that at least 90% of the particles have a weight average particle size of less than about 1000 nm when measured. More preferred is an effective average particle size of less than about 400 nm, or less than about 300 nm. In some embodiments an effective average particle size of less than about 100 nm is more preferred (col. 11, lines 47-62).

Method of making the aerosol preparation is described in columns 7-16. Examples are provided for making an aerosol preparation containing about 0.2% of beclomethasone dipropionate (col. 13).

Wood does not disclose that each droplet of the aerosol comprises at least one nonaparticulate drug particle, however it does teach that nanoparticles comprise insoluble therapeutic particles, and the minor variation would be a logical extension of Wood's disclosure.

Claims 51-64, 79-81 and 118 rejected under 35 U.S.C. 103(a) as being unpatentable over Wiedmann et al (5,747,001).

Wiedmann teaches an aerosol comprising droplets of an aqueous dispersion of nanoparticles, said nanoparticles comprising insoluble beclomethasone particles having a surface modifier on the surface thereof. A method of making an aerosol of a nanoparticle dispersion, said method comprising providing a suspension of said nanoparticles, nebulizing said suspension so as to form an aerosol. Also disclosed is a method of treating a mammal comprising the steps of forming an aerosol of an aqueous dispersion of nanoparticles, said nanoparticles comprising beclomethasone having a surface modifier on the surface thereof, administering said aerosol to the respiratory system of said mammal (col. 2, lines 20-38).

Wiedmann discloses that the droplets in the aerosols typically have a size less than about 50 microns in diameter (col. 2, lines 60-65). The beclomethasone is obtained

commercially and/or prepared by techniques known in the art. It is preferred that the particle size of the coarse beclomethasone be less than 100 microns (col. 6, lines 8-15).

Wiedman discloses that at lease 90% of the particles have a weight average particles size of less than about 400 nm when measured. In preferred embodiments the effective average particle size is less than about 300 nm, or less than about 100 nm (col. 10, lines 23-38). Also disclosed is that the aerosol preparation contains about 0.2% of beclomethasone dipropionate (col. 11).

Wiedmann does not disclose that each droplet of the aerosol comprises at least one nonaparticulate drug particle, however it does teach that nanoparticles comprise insoluble beclomethasone dipropionate particles, and the minor variation would be a logical extension of Wiedmann's disclosure.

Claims 84-101 and 118-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiedmann et al (5,747,001) as applied to claims 51-64, 79-81 above, in view of Dalby et al (5,202,110).

Wiedmann, discussed above, lacks specific teachings on pMDIs.

Dalby teaches delivery of beclomethasone dipropionate by metered dose inhalers containing non-CFC propellants. The preparation of Dalby contains beclomethasone dipropionate, surfactant and a non-CFC propellant. the aerosolized particles should have a small particle size, e.g. 0.1 to 10 microns (col. 2, lines 23-45).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of Wiedmann et al to have looked further in the art for a specific inhalation device, such as MDIs, as taught by Dalby, because of using an environmentally acceptable propellant, and because MDIs are small, hand-held devices, where patients can carry with them, and they are less costly to make.

Double Patenting

Claims 51-64, 79-81, 84-101 and 118-119 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09,190,138. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in both sets of claims is essentially the same and variations are obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Edwards et al (5,985,309) and Liversidge et al (5,145,684).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
September 30, 2002

JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616